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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/931,732

08/16/2001

Bob D. Brown

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05/19/2006

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2040 Main Street
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EXAMINER

Ashen, Jon Benjamin

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,732

Applicant(s)

BROWN ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 and 21-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions-necessitated by Amendment

1. Applicant's addition of new claims 38, 40, 42, 44, 46 and 48, in the communication filed 03/06/2006 has, upon reconsideration, necessitated the following Requirement for Restriction.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 36-48 are drawn to antisense oligonucleotides and ribozymes that are able to hybridize to two or more RNA molecules that different in sequence by one or more single nucleotide polymorphism in the target regions that hybridize to said antisense oligonucleotide and that comprise one or more non-naturally occurring base positioned in said antisense oligonucleotide or ribozyme to align with a single nucleotide polymorphism position in the target regions of the RNA molecules wherein the target RNA molecules are encode a human oncogene selected from the 8 genes listed in claims 38, 40, 42, 44, 46 and 48, classifiable in class 536, subclass 24.5.
3. Claims 37, 39, 41, 43, 45 and 47 link(s) the various inventions that are each of the antisense oligonucleotides or ribozymes that are targeted to each of the 8 different oncogenes as set forth in claims 38, 40, 42, 44, 46 and 48. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s),

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claims 37, 39, 41, 43, 45 and 47. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions in group I are related as products which share an alleged common utility of being antisense oligonucleotides or ribozymes, which are art recognized terms for inhibitory nucleic acids. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be

used to perform another utility. The products themselves are nucleotide sequences from 6 to about 50 nucleotides in length that comprise universal and/or degenerate bases in positions that align with single nucleotide polymorphisms shared by RNA strands of the same sequence. In the instant case, a compound that is a nucleic acid oligonucleotide that has a universal base in such a position can be used to perform another utility, which is as a hybridization probe to quantify the total expression of an RNA that is expressed as an allele, in order to establish a baseline for comparison of allele specific expression.

Therefore, claims 38, 40, 42, 44, 46 and 48 are is subject to an additional restriction since each is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention

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exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 38, 40, 42, 44, 46 and 48 specifically claim antisense oligonucleotide and ribozymes targeted to the 8 different RNAs expressed from 8 different oncogenes as listed. The antisense oligonucleotides and ribozymes claimed are therefore each considered to be unrelated, since each antisense oligonucleotide or ribozyme claimed is structurally and functionally independent and distinct for the following reasons: each antisense oligonucleotide or ribozyme has a unique nucleotide sequence and absent evidence to the contrary, each antisense oligonucleotide or ribozyme, upon binding one of the 8 different RNAs expressed from 8 different oncogenes as claimed, is expected to functionally modulate the activity of that different gene. One cannot be substituted for the other with the expectation that the same result would be achieved. As such the Markush/genus of oncogenes that are targets of the antisense oligonucleotides and ribozymes as claimed and as listed in claims 38, 40, 42, 44, 46 and 48, are not considered to constitute a proper genus, and are therefore subject to restriction.

Accordingly, applicant is required to elect one (1) oncogene from claims 38, 40, 42, 44, 46 and 48 that will be examined as the target of the antisense oligonucleotide and ribozymes now claimed and currently under examination. Note that this is not a species election.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

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folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

JANE ZARA, PH.D.
PRIMARY EXAMINER

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